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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,233	02/19/2004	Ross Jonathan Hamel	SYNT-0133	7395
53443 7590 12/14/2007 WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			EXAMINER COMSTOCK, DAVID C	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/14/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/783,233

Applicant(s)

HAMEL, ROSS JONATHAN

Examiner

David Comstock

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 10-30, 40, 48-65, 78-80, 82 and 87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 31-39, 41-47, 66-77, 81 and 83-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Objections***

Even though claims 10-30, 40, 48-65, 78-80, 82 and 87 have been withdrawn from consideration, it is noted that several of these claims have been improperly drafted such that they depend upon themselves. See, for example, at least claims 11, 12, 14, 16, 17, 18, 22, 26, 28, 29 and 30. This issue is raised in response to Applicant's request for rejoinder of any claims depending from any claim(s) that may be found to contain allowable subject matter. No such allowable subject matter has been identified in this action; nevertheless, even if it had been, the improperly numbered claims would remain a problem. Where numerous claims are clearly misnumbered, often others contain inaccurate dependencies and antecedent references. Therefore, Applicant should review all of the claims and make necessary corrections to the claim numbering and content if necessary.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7, 31-34, 41-45, 47, 66-69, 72-77, 81 and 83-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Standerwick et al. (3,072,118; of record) in view of Farley et al. (6,663,630).

Standerwick et al. disclose a fracture assembly comprising a reduction platform, e.g. 2, having receiving holes 28, a fragment manipulator, e.g. 8, having a bone engaging end 33, and a nut, e.g. 14, threadably and adjustably engaging the manipulator above the platform. The nut engages the top of the platform and the platform is between the nut and the bone engaging end of the manipulator. The second end of the manipulator includes a tool-engaging portion with a coupling surface 3. The manipulator includes a second outer diameter portion 30 that is larger than a first outer diameter portion 32 and comprises a diameter that is smaller than a receiving hole. With regard to claim 72, the device is positioned over bone and the fragment manipulator is inserted through the reduction platform. (See, e.g., Fig. 1 and col. 3, line 14 - col. 4, line 27.) The fragment manipulator is inserted into bone. The nut is threaded onto the fragment manipulator and is made to contact the platform. The nut draws the manipulator upward during adjustment. Standerwick et al. disclose the claimed invention except for disclosing the threads. Farley et al. disclose a fixation system wherein threaded bone screws are used in place of pins in order to securely engage the skull and eliminate the danger of loosening skull pins (see, e.g.: Figs. 3-5, 7-9, 11 and 18; col. 1, lines 60-63; col. 2, lines 25-27, 32 and 33; col. 3, lines 42-45; col. 5, lines 51, 52, 56 and 57; col. 6, lines 14-16; and col. 7, lines 19-20, 65 and 66). It would have been obvious to one having ordinary skill in the art at the time the invention was

made to provide the fracture assembly of Standerwick et al. with threaded bone screws instead of pins, in view of Farley et al., in order to securely engage the skull and eliminate the danger of loosening skull pins. The structure described in method claims 73-77, 81 and 83-86 has not been afforded patentable weight, since it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.D. 408 (1961).

Claims 5, 6 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Standerwick et al. (3,072,118; of record) in view of Farley et al. (6,663,630), as applied to claims 1 and 41 above, and further in view of Carol (4,955,891).

The device of the combination of Standerwick et al. and Farley et al. teaches the claimed invention except for the self-drilling threads. Carol discloses a system to be fixed on a skull and teaches the use of self-drilling screws 208 (see Fig. 9). The use of self-drilling screws reduces the number of steps required to secure the screws and consequently makes doing so easier and less time consuming. It would have been obvious to a person of ordinary skill in the art at the time of the invention to have provided the screws of the device of Standerwick et al. and Farley et al. with self-drilling threads, in view of Carol, in order to reduce the number of steps required to secure the screws and make doing so easier and less time consuming. It is also noted that the threads of the combination comprise portions of increasing diameter and constant diameter.

Claims 8, 9 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Standerwick et al. (3,072,118; of record) in view of Farley (6,663,630), as applied to claim 1 above, and further in view of Letendart et al. (6,432,109; of record).

The device of the combination of Standerwick et al. and Farley et al. discloses the claimed invention except for the nut comprising a spherical nose interface. Letendart et al. disclose a similar device having a nut 4 comprising a spherical nose interface 9 to allow the device to be easily adjusted in a desired direction and facilitate the procedure (see, e.g., Fig. 5 and col. 2, lines 1-8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the assembly of the device of Standerwick et al. and Farley et al. with a nut comprising a spherical nose interface, in view of Letendart et al., in order to allow the device to be easily adjusted in a desired direction and facilitate the procedure.

Claims 35, 36, 70 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Standerwick et al. (3,072,118; of record) in view of Farley (6,663,630), as applied to claims 34 and 69 above, and further in view of Bittner, Jr. (2,055,024; of record).

The device of the combination of Standerwick et al. and Farley et al. discloses the claimed invention except for the connection clamp and thumb wheel for the support system. Bittner, Jr. discloses a similar device comprising a connection clamp 6, 7, 8, 9 and a thumb wheel 5 for a support system to facilitate rapid adjustments and to promote proper healing (see, e.g., Fig. 1; col. 1, lines 15-17; and col. 4, lines 14 and 15). It

would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the assembly of the device of Standerwick et al. and Farley et al. with a connection clamp and thumb wheel for the support system, in view of Bittner, Jr., in order to facilitate rapid adjustments and to promote proper healing.

### ***Response to Arguments***

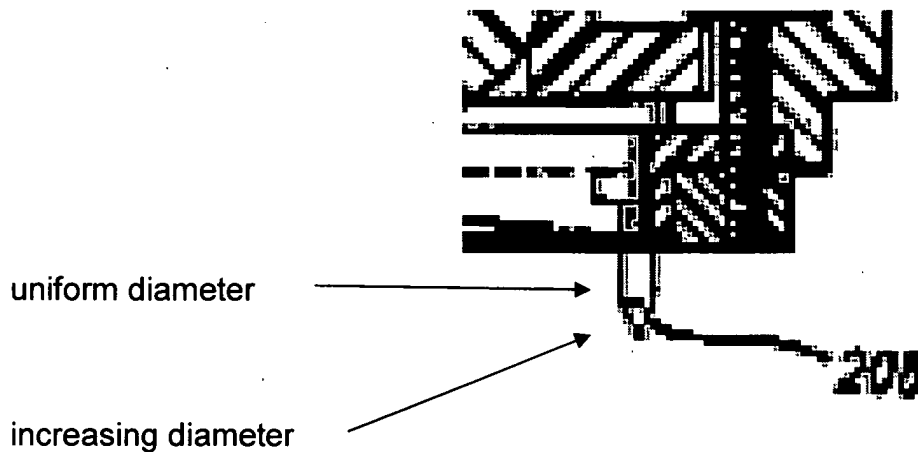
Applicant's arguments filed 06 September 2007 have been fully considered but they are not persuasive.

Applicant's comment that "not all bone screws are capable of being used to reduce bone fractures" (see Remarks, page 17, lines 5-6) does not constitute evidence that the threaded screws of Farley et al. would somehow not be at least capable of reducing bone fractures. It is noted that the very purpose of the threads is to engage bone and eliminate the danger of loosening skull pins (as already cited in the rejection). Applicant is reminded that screws must be rotated to be inserted and removed. Therefore, unless Farley et al. intended to just jerk the screws out and damage the skull, Examiner maintains that to remove the screws, the screws must be rotated out. That is all to say, the threads engage the bone (which, it should go without saying, is hard). Moreover, the threads were added for the express purpose of engaging the skull even more securely than skull pins. Finally, while Examiner maintains that the thread/bone interface of the combination is more than sufficient to perform virtually any intended use of reduction, the threaded screws of the combination is certainly capable of at least reducing, for example, a free bone fragment (e.g. a portion structurally

separated from the remainder of the broken pieces and/or the skull). Accordingly, it satisfies the claims. Regarding the method claims, it is further noted that, given the device of the aforementioned combination and a patient having a cranial fracture in need of reduction, it would be abundantly obvious to a surgeon of ordinary skill in the art to use the device to reduce the bone, or at the very least, obvious to try to use the device to reduce the bone, since it would have every appearance of being suitable to the task (e.g. due to the frame about the skull, the adjustable posts, the threaded screws, etc.).

Regarding dependent claim 6, indeed, as Applicant asserts, the *reference* is *silent* as to the construction of the screws (except to refer to them as “self-tapping screws 208”); however, if one *looks* at the figures (e.g., Fig. 14), one will clearly see that the self-tapping screws comprise a first portion having an increasing diameter and a second portion having a uniform diameter (see Detail View of Fig. 14 below). Since screws have threads, and this screw comprises both portions, it is considered to have threads having increasing diameter and having a uniform diameter on the respective portions. Also, note that they are not called “self-tapping *tips*,” or the like, but “screws.”





**Detail View**

In addition, the term “self-tapping” should not be overlooked. In order to be self-tapping, the tip must not only perform a cutting function, but also, it must perform an engaging and advancing function (i.e. it must have threads). Since the screws are there to perform an engaging function, it seems quite unreasonable to presume that the uniform diameter portion would be unthreaded. Even if--*arguendo*--the threads were not as claimed, it would have been abundantly obvious to a person of ordinary skill in the art to have modified the range of the size of the threads to facilitate entry and enhance engagement. Even belaboring the point seems to be unnecessary given the state and age of the art of screws--including those with pointed, threaded tips. .

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. Please leave a detailed voice message if examiner is unavailable. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

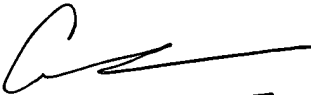
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Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock



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